

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 7177WOO1	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2004/036895	International filing date (<i>day/month/year</i>) 04 November 2004 (04.11.2004)	Priority date (<i>day/month/year</i>) 19 November 2003 (19.11.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant ABBOTT LABORATORIES			

- This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
- This REPORT consists of a total of 8 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.
- This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application
- The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 29, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 22 May 2006 (22.05.2006)
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PATENT COOPERATION TREATY

REC'D 10 MAR 2005

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From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2004/036895

International filing date (day/month/year)
04.11.2004

Priority date (day/month/year)
19.11.2003

International Patent Classification (IPC) or both national classification and IPC
A61B17/16, A61B17/88

Applicant
ABBOTT LABORATORIES

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/036895

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2004/036895

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 15-20

because:

- ☒ the said international application, or the said claims Nos. 15-20 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 15-20
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/036895

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-14
Inventive step (IS)	Yes: Claims	
	No: Claims	1-14
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 15-20 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1 Reference is made to the following documents:
D1: WO-A-8806023
D2: FR-A-2820630
D3: Mecron brochure B. "Osteosynthesis" 1979-80
- 2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT:
 - 2.1 Any self-tapping bone screw constitutes a bone tap. Therefore document D1 discloses:

A bone tap comprising a screw (1) suitable for introducing fluid into a bone (because it is cannulated), comprising:
a body;
a passage (3) through the body;
threading (4) located near an end of the body (and elsewhere); and
openings (4) through the threading in communication with the passage

as specified in claim 1.
 - 2.2 D2 shows self-tapping screws which are very similar to those of D1 and therefore also deprive the subject-matter of claim 1 of novelty.

3 The subject matter of claim 9 also is not new in the sense of Article 33(2) PCT:

3.1 Document D1 discloses:

A system, suitable for forming a threaded hole in a bone, comprising:
a tap (10) comprising a passage (15) and one or more openings;

(NB "a passage and one or more openings" is a confusing expression, and hence renders claim 9 unclear, Article 6 PCT, because a passage by definition must have an opening at at least one end, so it is not clear what if any further technical features are indicated by "one or more openings" in addition to "a passage")

and a driver (18),(24) configured to be couple to the tap

as specified in claim 9.

3.2 Moreover, for screw (1) to be insertable a driver must be configured to be coupled to its head (5), and this driver together with screw (1) constitute a system according to claim 9.

3.3 Furthermore an ordinary cannulated tap with a driver in the form of a cross-bar handle like that shown on page B33 of D3 ("Gewindeschneider mit Durchgangsbohrung Cannulated tap") has all the features listed in claim 9.

4 Dependent claims 2-8 and 10-14 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

4.1 The devices disclosed in D1 and D2 each have all the features of claims 2, 4 (no feature is indicated in the present application which tends to inhibit backflow of fluid any more than standard threading naturally does), 5 (especially D2), 6 and 8 (D1 figure 1 and D2 figures 3 both show regularly-spaced fenestrations)

- 4.2 D1 refers explicitly (page 8, line 6) to "chip-removal canals" i.e. flutes and besides, flutes, as specified in claim 3, are the standard means of achieving the capacity to tap, and are therefore obvious to incorporate in all the devices disclosed in D1-2
- 4.3 The devices of D1 have passages extending between their proximal and distal ends as in claim 7
- 4.4 The openings of the devices of all of D1-3 appear to be suitable for, and hence adapted to, allow delivery of bone cement (claim 10) and in D2 this is explicit
- 4.5 Figure 9 of D2 shows a variety of fluid delivery system tips which, because of their non-circular cross-sections, could also be used as drivers, some of which have resilient members formed as spring tabs, as specified in claims 11-12 of the application. (Claim 12 should dependent on claim 11, not 9, since the resilient member it refers to is first mentioned in claim 11). In any case, drivers which have resilient members to inhibit unintentional separation are known in the surgical art and are obvious to use with any kind of surgical screw.
- 4.6 The devices of all of D1-3 have openings apparently suitable to be used as fluid ports (claim 13) and for D1-2 this is explicitly the case
- 4.7 The systems of D1-2 include fluid delivery means (claim 14)